

CLAIMS:

1. An isolated polypeptide or a derivative, homologue, analogue or functional equivalent thereof wherein said polypeptide is obtainable from a species of *Mycobacterium* and which polypeptide is immunointeractive with sera from a human, animal or avian species exposed to 5 said species of *Mycobacterium* or its relative or antigenic parts thereof but which polypeptide is substantially not immunointeractive with sera from a human, animal or avian species not prior exposed to said species of *Mycobacterium* or its relative or its antigenic parts.

2. An isolated polypeptide according to claim 1 wherein the species of *Mycobacterium* is selected from *Mycobacterium* is *M. tuberculosis*, *Mycobacterium avium*, *Mycobacterium microti*, *Mycobacterium leprae*, *Mycobacterium lepraeumurium*, *Mycobacterium paratuberculosis*, *Mycobacterium ulcerans*, *Mycobacterium marinum*, *Mycobacterium smegmatis*, *Mycobacterium intracellulare*, *Mycobacterium xenopi*, *Mycobacterium chelonei*, *Mycobacterium fortuitum*, *Mycobacterium farcinogenes*, *Mycobacterium flavum*, *Mycobacterium haemophilum*, *Mycobacterium kansasii*, *Mycobacterium phlei*, 15 *Mycobacterium scrofulaceum*, *Mycobacterium senegalense*, *Mycobacterium simiae*, *Mycobacterium thermoresistible*, and *Mycobacterium xenopi*.

3. An isolated polypeptide according to claim 2 wherein the species of *Mycobacterium* is *M. tuberculosis*. *JK*

4. An isolated polypeptide or a derivative, homologue, analogue or functional equivalent 20 thereof wherein said polypeptide is obtainable from *M. tuberculosis* or a related organism and which polypeptide is immunointeractive with sera from a human previously exposed to *M. tuberculosis* or an antigenic extract therefrom but is substantially not immunointeractive with human sera not previously exposed to *M. tuberculosis* or a antigenic extract thereof.

5. An isolated polypeptide according to claim 4 wherein the human exposed to *M. tuberculosis* has active pulmonary or extra-pulmonary tuberculosis. *JK*

6. An isolated polypeptide according to claim 4 or 5 wherein the polypeptide has a 25 molecule weight of from about 5 kDa to about 100 kDa.

7. An isolated polypeptide according to claim 6 wherein the molecular weight is selected from about 10 to 20 kDa, 28 to 38 kDa, 38 to 48 kDa, 53 to 63 kDa and 55 to 65 kDa.

8. An isolated polypeptide comprising an amino acid sequence selected from <400>2, <400>4, <400>6, <400>8, <400>10 or an amino acid sequence having at least 60% similarity to any one of said sequences.

9. An isolated polypeptide encoded by a nucleotide sequence selected from <400>1, <400>3, <400>5, <400>7, <400>9 or an nucleotide sequence having at least 60% similarity to any one of said sequences or a nucleotide sequence capable of hybridizing to any one of said sequences under low stringency conditions at 42°C.

10. A method of isolating a polypeptide from *Mycobacterium* species said method comprising culturing cells of said *Mycobacterium* species in a growth medium to increase the number of cells to a sufficient population, harvesting said cells and subjecting said cells to protein extraction techniques to extract protein from said cells, fractionating the extracted protein and subjecting said protein to binding analysis with antibodies to said *Mycobacterium* species or antigenic portions thereof and isolating the polypeptides to which antibodies interact.

15 11. A method according to claim 10 wherein the *Mycobacterium* species is *M. tuberculosis*.

12. A method according to claim 10 or 11 wherein the growth medium is Lowenstein-Jensen medium.

13. A method according to claim 10 wherein the binding analysis is conducted by Western blotting and other immunoassay procedures.

20 14. An isolated nucleic acid molecule comprising a sequence of nucleotides encoding or complementary to a sequence encoding a polypeptide obtainable from a species of *Mycobacterium* and which polypeptide is immunointeractive with sera from a human, animal or avian species exposed to said species of *Mycobacterium* or its relative or antigenic parts thereof but which polypeptide is substantially not immunointeractive with sera from a human, animal or avian species not prior exposed to said species of *Mycobacterium* or its relative or its antigenic parts.

15. An isolated nucleic acid molecule according to claim 14 wherein the *Mycobacterium* species is *M. tuberculosis*.

16. An isolated nucleic acid molecule according to claim 15 wherein the nucleotide

sequence encodes an amino acid sequence substantially as set forth in <400>1, <400>3, <400>5, <400>7, <400>9 or an amino acid sequence having at least 60% similarity thereto.

17. An isolated nucleic acid molecule according to claim 15 wherein the nucleotide sequence is substantially as set forth in <400>1, <400>3, <400>5, <400>7, <400>9 or an nucleotide sequence having at least 60% similarity to any one of said sequences or a nucleotide sequence capable of hybridizing to any one of said sequences under low stringency conditions at 42°C.

18. An antibody specific to the polypeptide according to ~~any one of claims 1 to 9~~.

19. An antibody according to claim 18 wherein the antibody is a monoclonal antibody.

10 20. A method for detecting the presence of *M. tuberculosis* such as in a patient suffering from tuberculosis said method comprising contacting a biological sample from a patient or subject with an antibody specific for a polypeptide from said *M. tuberculosis* and detecting a complex between said polypeptide and said antibody.

15 21. An assay device for *M. tuberculosis* comprising a solid support having immobilized thereon one or more polypeptides obtainable from *M. tuberculosis* or derivatives, homologues, analogues or antigenic equivalents thereof and a portion of said solid support adapted for receiving a sample from a human subject to be tested wherein said sample would contain an antibody specific for said *M. tuberculosis* polypeptide if said subject has been exposed to *M. tuberculosis* wherein upon contact between the antibody from the subject and the immobilized 20 polypeptide, a complex forms and said complex is detected by an anti-human immunoglobulin labelled with a reporter molecule.

22. Use of a polypeptide according to ~~any one of claims 1 to 9~~ in the manufacture of a medicament for the treatment of *Mycobacterium* infection in a human, animal or bird.

23. Use according to claim 22, wherein the *Mycobacterium* is *M. tuberculosis* and the 25 infection in human.

24. A method for treating or preventing infection by *Mycobacteria* species in a human, animal or avian species said method comprising administering to said human, animal or avian species an immune response stimulating an effective amount of a polypeptide according to any one of claims 1 to 9.

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25. A method according to claim 24 wherein the species of *Mycobacterium* is *M. tuberculosis* and the infection is in humans.

26. A method according to claim 24 wherein the infection is active pulmonary tuberculosis or extra-pulmonary tuberculosis.